



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Falsification of Blood
Pressure Readings at the
Berea Community Based
Outpatient Clinic

Lexington, Kentucky



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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a report that a primary care provider (PCP-1) at the Berea, Kentucky, Community Based Outpatient Clinic (CBOC) of the Lexington VA Medical Center (Facility) falsely documented patients' blood pressure (BP) readings. The purpose of this rapid response review was to assess the extent to which PCP-1 falsely documented BP readings to reflect relatively normal values and whether those actions placed patients with hypertension (HTN) at risk. The OIG team also analyzed how the falsifications went undetected and unreported, and assessed Facility leaders' response to PCP-1's practices and the associated quality of care concerns.

In late December 2017, several employees at the Berea CBOC reported to Facility leaders that PCP-1 was documenting the same repeat BP, 128/78, for multiple patients. Facility leaders' initial review found that 83 percent of PCP-1's BP rechecks from June 1 to November 29, 2017, were listed as 128/78. However, BP readings from other Berea CBOC providers demonstrated a pattern consistent with reasonable BP deviations over time. Facility leaders subsequently contacted 10 patients who had recently been seen by PCP-1 and had documented BP rechecks of 128/78. Eight of those patients told Facility staff that PCP-1 did not recheck their BPs. Facility leaders summarily suspended (temporarily restricted) PCP-1's clinical privileges and promptly reassigned PCP-1 to non-clinical duties.

The OIG team reviewed more than 5,000 of PCP-1's patient encounters from October 1, 2015, through December 26, 2017. Of these, 1,370 were primary care encounters during which the patients had diagnoses that placed them at greater risk for adverse clinical outcomes (defined in this report as death, a change in the course of treatment or diagnosis, or a significant change in the patient's level of care) if/when their BPs were not well controlled. The OIG's review found that in 1,364 of the 1,370 encounters (99.5 percent), PCP-1 documented repeat BPs of 128/78.

PCP-1 confirmed documenting the same BP readings. PCP-1 also failed to provide basic HTN management to high-risk patients. Sixty-four of the 1,370 encounters noted previously were referred to an OIG physician for review as the patients met the OIG team's preselected high-risk criteria. Uncontrolled HTN for this group of patients would increase the likelihood of adverse clinical outcomes, including death. For this group of 64 patients, the OIG noted that PCP-1 rarely added or changed medications for HTN in instances when it would have been appropriate. When PCP-1 added medications, laboratory work for the patients to ensure that the medications were not causing harm to organs such as the kidneys was inconsistently ordered. Further, PCP-1 scheduled nine-month follow-up appointments for most patients irrespective of the complexity of their conditions and sufficiency of BP control. PCP-1 also documented secondary HTN (elevated BP from an underlying cause) for multiple patients when the OIG found no evidence of a workup

for secondary HTN in the electronic health record (EHR). Lastly, despite PCP-1's assertion that home BP cuffs were routinely ordered, OIG inspectors did not find evidence of this. PCP-1's actions adversely impacted several patients and placed other patients at risk for adverse clinical outcomes.

In assessing the risk of harm from PCP-1's BP falsification and poor management of HTN, the OIG considered the American College of Cardiology (ACC) and American Heart Association (AHA) joint guidelines¹ on 10-year risk estimates for developing atherosclerotic cardiovascular disease (ASCVD) events such as a stroke or heart attack. Of the 64 high-risk patients reviewed by the OIG physician, all had diagnoses of HTN and diabetes with BP greater than 160/100. Forty-three of these patients were aged 40 to 79 and therefore met the criteria to apply the ASCVD calculator. The ASCVD calculator results reflected the 43 patients' collective average 10-year ASCVD risk was 53 percent using their initial BP readings, with a low of 24.6 percent and a high of 82.2 percent. These 43 patients had marked systolic BP² elevations with significant risk factors of ASCVD. The goal is to try to optimize treatment to achieve the lowest systolic BP number as possible to lower risk, and the ACC/AHA joint guidelines recommend consideration of intervention starting around 7.5 percent. However, PCP-1's inaction and inadequate surveillance related to HTN, exposed patients to continued risk for adverse clinical outcomes.

PCP-1 told the OIG team that documentation of the 128/78 BP readings was done to "turn off" the clinical reminder and provided several rationales for this conduct. The OIG team did not find the explanations plausible and concluded that PCP-1's falsification of BP readings was most likely an effort to reduce workload as normal BPs would not require further intervention or documentation.

The Facility did not have processes in place to validate performance measure data. Per Veterans Health Administration (VHA) guidance, Primary Care Management Module coordinators are supposed to validate the accuracy of the data impacting VHA Support Service Center (VSSC) performance monitor reports monthly.³ However, Facility staff did not take additional steps to validate the underlying data, which would have uncovered PCP-1's falsified BP documentation and deviation from accepted practices. OIG learned that PCP-1 received a performance award in

¹ Paul K. Whelton, et al. *2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCN A Guideline for The Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines*. Hypertension. 2017.

² Systolic BP indicates how much pressure the blood is exerting against the walls of the blood vessels when the heart beats.

³ VHA Handbook 1101.02, *Primary Care Management Module (PCMM)*, April 21, 2009 was rescinded and replaced by VHA Directive 1406, *Patient Centered Management Module (PCMM) for Primary Care*, June 20, 2017. While VHA Handbook 1101.02 specified a monthly review, VHA Directive 1406 does not specify a timeframe for this comparative analysis. VHA Directive 1406 requires "[c]ompleting comparative analysis of VSSC reports or data sets with local PCMM data to identify data variance and ensure data integrity."

2016, partially based on achieving the HTN measure; however, PCP-1 did not receive an award in 2017. Clinical privileges are decided from performance of many metrics, of which HTN management is one. If the totality of metrics was adequate but HTN was not, clinical privileges would likely continue.

While PCP practices varied depending on circumstances, licensed practical nurses (LPN) at the Berea CBOC were generally tasked with rechecking BPs that were elevated during patient visits, and notifying the PCP of persistently elevated BPs. PCP-1's LPN told the OIG that when rechecking elevated initial BPs, the LPN only documented the "better" (lower) BP. The OIG team confirmed through EHR review that the LPN rarely documented more than one BP. This practice was inconsistent with VHA requirements⁴ and was contrary to safe and appropriate patient care.

The OIG concluded that it was more likely than not that PCP-1 and the LPN assigned to PCP-1's team knew, or should have known for at least the last several years, about each other's deficient practices due to their close working relationship, the frequency and duration of PCP-1 documenting 128/78, and the frequency of the LPN not documenting a second BP reading after an elevated initial BP reading. Nevertheless, staff outside of PCP-1's team identified and reported the concerns to Facility leaders.

Facility leaders took prompt and appropriate steps to evaluate PCP-1's actions and mitigate risk to patients. After PCP-1's clinical privileges were suspended, PCP-1's patients were reassigned to other providers. Facility clinicians started EHR reviews to assess whether patients were at risk for, or had experienced adverse clinical outcomes due to, PCP-1's misconduct. Facility leaders also established an HTN clinic to follow up with PCP-1's patients; conducted additional in-house clinical reviews of PCP-1's entire patient panel and referred several cases to external reviewers; initiated an expedited, five-day, State Licensure Board report; and conducted a clinical disclosure. Facility leaders were evaluating the initiation of administrative actions related to PCP-1, as appropriate.

The OIG made seven recommendations to the Facility Director related to administrative actions, patient care follow-up, data integrity, policy and procedure development, and staff training.

⁴ VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided an acceptable action plan. (See Appendixes C and D, pages 27-31 for the Directors' comments.) The Facility provided supporting documentation and the OIG considers recommendations 1, 2, 3, and 7 closed. The OIG will follow up on the remaining recommendations and planned actions until they are completed.



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Abbreviations

ASCVD	atherosclerotic cardiovascular disease
BP	blood pressure
CBOC	community based outpatient clinic
COS	chief of staff
DBP	diastolic blood pressure
EHR	electronic health record
FY	fiscal year
HTN	hypertension
LPN	licensed practical nurse
OIG	Office of Inspector General
OPPE	ongoing professional practice evaluation
PCP	primary care provider
SBP	systolic blood pressure
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
VSSC	VHA Support Service Center



Introduction

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a report that a primary care provider (PCP-1) falsely documented patients' blood pressure (BP) readings at the Berea, Kentucky, Community Based Outpatient Clinic (CBOC) of the Lexington VA Medical Center (Facility).

Background

The Facility is a general medicine and surgery facility composed of two divisions—Leestown and Cooper Drive—with CBOCs located in Berea, Hazard, Morehead, and Somerset, Kentucky. The Facility operates 174 beds and completed more than 517,000 outpatient visits in fiscal year (FY) 2017; more than 15,000 of those visits were completed at the Berea CBOC. The Facility is part of Veterans Integrated Service Network (VISN) 9.

Primary Care

Primary care is the provision of integrated, accessible healthcare services and includes diagnosis and management of acute and chronic biopsychosocial conditions, health promotion, disease prevention, and overall care management, among other services.⁵ Patients depend on their PCPs to provide timely health care and to minimize future health issues through medical advice and intervention. Formulation of the PCP's plan of care entails clinical decision-making by assessing patients' risks for certain conditions. For example, a strong family history of heart disease may affect the patient's care plan for cardiovascular screenings. Important PCP goals in patient care are to prevent disease, manage conditions, and provide the highest level of care in the safest way possible. To that end, PCPs must understand future conditions that can develop if inadequate disease management occurs.

VA PCPs must maintain accurate, timely, relevant, and complete electronic health records (EHR), which contain sufficient recorded information to serve as a basis to plan patient care, support diagnoses and treatment, and measure outcomes.⁶

Four patient aligned care teams (PACT) are based at the Berea CBOC. Each team consists of a PCP (physician), registered nurse, licensed practical nurse (LPN), and medical support assistant

⁵ VHA Handbook 1101.10(1), *Patient Aligned Care Team (PACT) Handbook*, amended May 26, 2017.

⁶ VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015.

(clerical/administrative position). PCP-1 was a long-tenured provider who served at the Berea CBOC.

High Blood Pressure and Its Management

High blood pressure, also known as hypertension (HTN), is a condition when the force of blood pushing against the walls of the blood vessels is consistently too high.⁷ Systolic blood pressure (SBP) indicates how much pressure the blood is exerting against the walls of the blood vessels when the heart beats. Diastolic blood pressure (DBP) indicates how much pressure the blood is exerting against the walls of the blood vessels while the heart is resting between beats. BP is recorded as SBP/DBP millimeters of mercury (mm Hg). Normal BP is defined as less than or equal to (\leq)120/ \leq 80 mm Hg;⁸ elevated BP is 120-129/ \leq 80 mm Hg; and pre-HTN is 130-139 mm Hg SBP or 80-89 mm Hg DBP.

HTN, diagnosed when the BP is consistently 140/90 or higher, is usually asymptomatic; therefore, routine screening is important in order to identify the condition. To control and manage HTN, clinical providers may recommend lifestyle changes such as improved diet, regular exercise, or smoking cessation. The use of BP-lowering medications may be recommended for some patients. When HTN is not controlled, or the patient is in a hypertensive crisis,⁹ patients are at risk for heart attack, stroke, peripheral arterial diseases, kidney disease, and congestive heart failure. HTN treatment requires lowering BPs to an acceptable endpoint to lessen the chance of future cardiovascular and other negative events.

Accurate measurement and recording of BP is essential. According to a 2017 American College of Cardiology/American Heart Association task force:

Because individual BP measurements tend to vary in an unpredictable or random fashion, a single reading is inadequate for clinical decision-making. An average of two to three BP measurements obtained on two to three separate occasions will minimize error and provide a more accurate basis for estimation of BP.¹⁰

At the Berea CBOC, typical practice involved an LPN taking the patient's BP at the beginning of each primary care appointment and documenting the reading in the EHR. While PCP practices varied depending on circumstances, LPNs were generally tasked with rechecking BPs that were elevated during the visit and notifying the PCP of persistently elevated BPs.

⁷ Approximately 78 million adults have HTN in the United States.

⁸ According to the Mayo Clinic, average BP goals can vary depending on age and disease burden.

⁹ Hypertensive crisis is a severe increase in BP to 180 SBP or higher or a DBP of 120 or higher.

¹⁰ Paul K. Whelton, et al. *2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines.*

Clinical Reminders

VA's Clinical Reminder System, a component of the EHR, assists with clinical decision-making and can alert providers to perform certain tests or other evaluations that will enhance the quality of care for specific conditions. Clinical reminders allow providers to easily view patient-specific information, the date specific patient tests or evaluations were performed, and track and document when care has been delivered. Providers respond to the reminders by placing relevant orders or recording clinical activities in the patients' EHR.¹¹ When a provider documents a diagnosis of HTN in the EHR problem list, the HTN-related clinical reminder is added to the list of reminders for that patient. The clinical reminder for a BP of $\geq 140/90$ asks the provider what they would like to do—change medications, order laboratory tests, or make additional referrals. The provider can choose to ignore or acknowledge the reminder. A normal BP value on recheck would “turn off” the reminder for that visit or until another elevated BP was documented.

Sequence of Events and Reported Concerns

In December 2017, several employees at the Berea CBOC reported to Facility leaders that PCP-1 was documenting the same repeat BP, 128/78, for multiple patients. Specifically, after the LPN documented the initial BP reading, PCP-1 then documented a repeat BP of 128/78. An initial review by the Facility's PACT Coordinator found “a significant trend of non-physiologic blood pressure recordings”¹² related to PCP-1, in that 83 percent of 339 BP rechecks were listed as 128/78.¹³ Facility leaders reviewed and graphed the patients' BP ranges for Berea CBOC providers, and while PCP-1's data was largely “flat” (reflecting few variations), BPs for other Berea CBOC providers (PCPs 2, 3, and 4) demonstrated a pattern consistent with normal deviations based on variations in the patients' BPs over time. Facility leaders subsequently contacted 10 patients who had recently been seen by PCP-1. These patients' EHRs reflected that PCP-1 rechecked and recorded the BPs after the initial check by an LPN. According to Facility leaders, PCP-1 reported rechecking each of the patients' BPs and documenting the new readings as 128/78. However, eight patients interviewed told Facility staff that PCP-1 did not recheck their BPs.¹⁴

When reporting this issue, the Chief of Staff (COS) told OIG investigators that the falsified BPs could negatively affect patient safety and treatment due to the patients not receiving medications and physician guidance to manage HTN. The COS also expressed concern that the falsified BPs,

¹¹VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015. A clinical reminder is the documentation tool “that acts as a template for documenting appropriate actions taken related to a given clinical reminder. The documentation of responses to a reminder, including progress note text, entry of orders, entry of vital signs, or other data elements, is part of the patient health record.”

¹² OIG interpreted this term to mean the blood pressure measurements were not consistent with normal functioning.

¹³ The PACT Coordinator's review period was June 1 to November 29, 2017.

¹⁴ Of the remaining two patients, one said PCP-1 did recheck his BP and the other could not remember.

which could have appeared to improve PCP-1's performance metrics, may have improperly factored in to the Facility's payment of PCP-1's performance bonus. Facility leaders summarily suspended (temporarily restricted) PCP-1's clinical privileges and reassigned PCP-1 to non-clinical duties.

On January 3, 2018, OIG's Office of Healthcare Inspections received a referral from the OIG's Office of Investigations about the COS's reported concerns.

The purpose of this inspection was to assess the extent to which PCP-1 falsely documented BP readings to reflect relatively normal values and whether those actions placed patients with HTN at risk for poor medical outcomes. The OIG team also analyzed how the BP falsifications went undetected and unreported, and assessed the Facility leaders' response to PCP-1's practices and the associated quality of care concerns.

Scope and Methodology

The OIG team initiated the review in January 2018. OIG inspectors conducted a site visit April 11–12, 2018. The data review included selected documents from October 1, 2015, through April 12, 2018.

Prior to the site visit, the OIG team interviewed the Facility Director, COS, Chief of Primary Care, several Berea CBOC nurses, and PCP-2 by telephone. During the site visit, the OIG team interviewed PCP-1 and several additional employees with knowledge of the issues.

The OIG team reviewed relevant Facility policies, VHA directives and handbooks, Facility quality and internal management reports, privileging data for PCP-1, and other documents relevant to the reported concerns. The OIG team performed EHR reviews involving over 5,000 primary care encounters of patients on PCP-1's panel for the period October 1, 2015, through December 26, 2017 (study period).¹⁵ The OIG team identified and focused on 1,370 encounters that included diagnoses from higher risk groups: primary or secondary HTN, diabetes mellitus, congestive heart failure, and atherosclerotic cardiovascular disease (ASCVD) (review population).¹⁶ The potential for adverse clinical outcomes¹⁷ is greater in the higher risk groups. For comparison purposes, the OIG team reviewed primary care encounters (October 1 through

¹⁵ The OIG identified completed encounters using stop codes 322, 323, and 350 within VHA's primary care clinic group.

¹⁶ The OIG chose to focus the review on these chronic conditions because of their high prevalence within the veteran population and because of the availability of nationally recognized guidelines for treating these conditions. Primary or secondary diagnoses were identified using selected International Classification of Diseases, Tenth Edition (ICD 10) codes that went into effect October 1, 2015.

¹⁷ Within the context of this report, the OIG considered an adverse clinical outcome to be death, a change in the course of treatment or diagnosis, or a significant change in the patient's level of care.

December 31, 2017) with associated BP readings for Berea CBOC providers PCP-2, PCP-3, and PCP-4.

The OIG referred this case for possible criminal prosecution; however, the case was declined by the United States Attorney for the Eastern District of Kentucky.

In this report, the OIG has generalized narratives and case scenarios and de-identified protected patient information. During the on-site visit, the OIG team met with Facility clinical leaders and the Facility Director to discuss the cases included in this report and provided detailed written case summaries to allow leaders to fully understand the sequence of events and the OIG's concerns about the cases.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Patient Case Summaries

Patient W

Patient W, who was over 60, had a history of [diabetes](#) and HTN. In early February 2016, PCP-1 saw Patient W for a routine follow-up. At 9:30 a.m., the LPN obtained Patient W's BP several times and documented 223/88, 234/134, and 217/90. Patient W's medications included medications for BP control and diabetes. PCP-1 documented a recheck BP reading of 128/78 with a statement that "[t]he patient is being evaluated for resistant or secondary causes for hypertension." PCP-1's assessment documented that HTN was controlled and made no medication changes. PCP-1 ordered an [electrocardiogram \(EKG\)](#) for "[labile hypertension](#)." No acute changes were reported on the EKG. PCP-1 requested a nine-month follow-up appointment.

Nine months later, Patient W was admitted to a non-VA hospital for uncontrolled HTN and chest pain. Patient W's initial BP in the non-VA hospital was 220/103. The non-VA hospital cardiologist diagnosed Patient W with an [acute myocardial infarction](#), completed a [heart catheterization](#), and placed two [cardiac stents](#). The catheterization report reflected no [thrombus](#). Medical staff at the non-VA hospital added another drug for BP control.

Approximately two weeks later, PCP-1 evaluated Patient W after placement of the cardiac stents. At 9:30 a.m., Patient W's BP was recorded as 219/117. PCP-1 completed a history and physical. Patient W's medications included two medications for BP control, and one medication for diabetes. PCP-1 documented a second BP reading of 128/78 at 9:59 a.m. PCP-1 made no changes to the medications and requested a nine-month follow-up appointment.

Patient X

Patient X, who was over 70, had a history of diabetes and HTN. In late 2016, PCP-1 evaluated Patient X for a routine follow-up appointment. A nurse obtained Patient X's BP and documented 190/106 at 10:30 a.m. PCP-1 then completed a history and physical. Patient X was taking medication for diabetes but not for BP. PCP-1 documented a second BP reading of 128/78 at 10:41 a.m. and requested a nine-month follow-up appointment.

Approximately seven months later, providers in the Facility's emergency department (ED) evaluated Patient X for altered mental status. A [computed tomography \(CT\)](#) scan of the head indicated an [intracerebral hemorrhage](#) with evidence of mild compression of the brain from the bleed. Patient X was stabilized and transferred by medical staff to a non-VA hospital. Patient X was discharged from the non-VA hospital on two medications for BP control.

Two months later, PCP-1 saw Patient X for a routine follow-up appointment. Patient X's initial BP was documented as 170/82 at 2:30 p.m. PCP-1 completed a history and physical and documented, "[Patient X] was hospitalized [two months ago] for [acute stroke](#) and required [tPA \[tissue plasminogen activator\]](#) to reverse the stroke." Non-VA hospital records did not document

tPA use. PCP-1 documented a second BP reading of 128/78 at 2:56 p.m. PCP-1 did not adjust medications. PCP-1 requested a nine-month follow-up appointment.

Patient Y

Patient Y, who was also over 70 years old, had a history of HTN and diabetes. In 2015, providers at the Facility's ED evaluated Patient Y for partial blindness over the past day. Patient Y's BP in the ED was recorded as 140/69. A [neurologist admitted Patient Y to the Facility after](#) diagnosing Patient Y with an [occipital stroke](#). Hospital staff monitored Patient Y and added aspirin for stroke prevention and medications to control [cholesterol](#) and diabetes. Patient Y's BP medications were continued. Patient Y was discharged two days later.

Approximately five months later, PCP-1 evaluated Patient Y during a routine follow-up; it was the first primary care visit since Patient Y's stroke. PCP-1 did not reference the stroke. Patient Y's initial BP was 159/67 at 10:30 a.m. At 11:12 a.m., PCP-1 repeated the BP and documented 128/78. PCP-1 made no medication changes and requested a nine-month follow-up appointment.

In 2017, PCP-1 evaluated Patient Y during a routine follow-up appointment. PCP-1 did not reference the 2015 stroke. Patient Y's initial BP was documented as 145/60. Twenty-four minutes later, PCP-1 repeated the BP and documented 128/78. PCP-1 made no medication changes and requested a nine-month follow-up appointment.

Approximately 10 months later, PCP-1 evaluated Patient Y during a routine follow-up appointment. PCP-1 did not reference the 2015 stroke. The LPN obtained Patient Y's BP and documented 180/93 at 12:30 p.m. At 12:50 p.m., PCP-1 repeated the BP and documented 128/78. PCP-1 made no medication changes and requested a nine-month follow-up appointment.

Patient Z

Patient Z, who was over 50 years old, had been enrolled in PCP-1's clinic since 2010. Patient Z had elevated BPs and at least one recheck documented as 128/78 during OIG's study period, but in this case, PCP-1 did add medication to the treatment plan. However, during OIG's review of the EHR, it was determined that Patient Z did not receive adequate follow-up from PCP-1 regarding Patient Z's [osteosarcoma](#), a form of bone cancer. Patient Z's case summary and OIG's analysis of care deficits can be found in [Appendix A](#).

Inspection Results

Issue 1: Falsification of BP Readings and Clinical Impact on Patients

Based on EHR reviews, the OIG team determined that PCP-1 documented 128/78 (generally normal BP) nearly 100 percent of the time when reportedly rechecking BPs of patients with initially elevated BP readings. PCP-1's actions adversely impacted several patients and placed hundreds of other patients at risk for adverse clinical outcomes. This section of the report focuses on

- The extent of BP falsification, which in the context of this report refers to made-up or misrepresented BP readings;
- The impact of the BP falsification and HTN mismanagement on high risk patients; and
- PCP-1's explanation for the falsified BP documentation.

Scope of False BP Documentation

Of the more than 5,000 patient encounters reviewed, the OIG team identified 1,370 completed primary care encounters¹⁸ from October 1, 2015, through December 26, 2017, where the patient had a diagnosis of HTN with many also having diabetes mellitus, congestive heart failure, or ASCVD. OIG's review found that in 1,364 of the 1,370 encounters (99.5 percent), PCP-1 documented BPs of 128/78.^{19,20} As PCP-1's patients had different disease burdens, health statuses, and treatment regimens, a BP reading of 128/78 occurring at the frequency noted is highly improbable.

Impact of BP Falsification and HTN Mismanagement on Patients

PCP-1 not only falsified BP readings, but also failed to provide HTN management to high-risk patients. Multiple patients experienced poor care or negative outcomes, including an acute cardiac event (see Patient Case Summaries).

¹⁸ The OIG identified completed encounters using stop codes 322, 323, and 350 within VHA's primary care clinic group.

¹⁹ Between October 1, 2015, and December 31, 2016, PCP-1 documented a 128/78 BP reading 575 times and between January 1, 2017, and December 26, 2017, PCP-1 documented a 128/78 BP reading 789 times. The OIG team also found that PCP-1 repeatedly documented BP readings of 138/78 during the review period (133 times).

²⁰ OIG did not independently contact patients to assess whether their BPs *were* taken and the readings falsified or whether the BPs *were not* taken and the BPs were fabricated. When interviewed by OIG, PCP-1 admitted to sometimes rechecking BPs and other times not rechecking BPs.

OIG's Analysis of High-Risk Patient Cases

Of the 1,370 encounters reviewed, 327 had initial BP readings, as documented by nursing personnel, of $\geq 160/100$. Sixty-four of the 327 encounters were referred to the OIG physician for review as they met the OIG team's preselected high-risk criteria.²¹

The OIG physician found significant care concerns related to the 64 patients reviewed. All had diagnoses of HTN and diabetes. Several had histories of a previous stroke, myocardial infarction, prior coronary stents, [cardiac bypass](#) operations, or [aortic aneurysms](#). Uncontrolled HTN for this group of patients would increase the likelihood of a repeat stroke, another cardiac event, or an aortic rupture, all of which could place patients at risk of death. For this high-risk population, the OIG team noted that PCP-1

- Rarely added or changed medications in instances when it would have been appropriate;
- Inconsistently ordered laboratory work when medications were added, to ensure that the medications were not causing harm to organs such as the kidneys;
- Scheduled nine-month follow-up appointments for most patients irrespective of the complexity of their conditions and sufficiency of BP control. Of the 64 high-risk patients in OIG's sample, PCP-1's follow-up for 47 of those patients was to "return in 9 months." By applying a single standard for nine-month surveillance to those patients at high risk for coronary²² or cerebrovascular events,²³ the potential risks for adverse clinical outcomes may not be adequately controlled;
- Documented secondary HTN for multiple patients when there was no evidence of a workup for secondary HTN. Secondary HTN is elevated BP coming from an underlying, often correctable cause. By documenting a workup was in progress for secondary HTN, the clinical reminder would "turn off" for high BP readings, which defeats one intent of a clinical reminder—to consider and work up secondary causes of HTN; and

²¹ Criteria for referral to the OIG physician included any patient with diagnosis of HTN, elevated BP readings of 160/100 or higher, and one or more of the target diagnoses (diabetes, congestive heart failure, and/or cardiovascular disease). All patients were prescribed medications associated with the diagnosis of HTN and one or more of the target diagnosis(es), the BP was not well-controlled (remained persistently elevated), and/or there was no documented evidence that PCP-1 acknowledged the elevated BP readings.

²² Coronary events, for this report, are defined as myocardial infarction, ischemic heart failure, unstable angina, or sudden death.

²³ A cerebrovascular event involves the sudden death of brain cells due to lack of oxygen when the blood flow to the brain is impaired by blockage or rupture of an artery to the brain.

- Reported routinely issuing home BP cuffs.²⁴ However, PCP-1's notes did not reflect home BP monitoring as part of the patient's treatment and management plan. Of the 64 high-risk patients in OIG's sample, only one had a BP cuff ordered and education for its use documented.

The OIG team did not have similar concerns about the other Berea CBOC providers. In late 2017, PCP-1's panel size was within VHA guidelines and the percentage of hypertensive patients on PCP-1's panel was similar to PCP-2, PCP-3, and PCP-4. The OIG team evaluated the practice patterns of PCPs 2, 3, and 4 related to HTN management. For the first quarter FY 2018 (October 1 through December 31, 2017), 746 encounters met the same criteria applied to the review population for PCP-1. In 51 encounters, patients had a BP documented as $\geq 160/100$. In all but one encounter, PCPs 2, 3, and 4 acknowledged the elevated BP by either documenting a possible reason for the reading or changing the plan of care.

OIG's Concerns of Poor Care and Outcomes of Patients W, X, and Y

Patients W, X, and Y represent specific examples of poor HTN management and possible adverse clinical outcomes.

Patient W had several elevated BP readings as recorded by the LPN (223/88, 234/134, and 217/90) during an appointment in early 2016. PCP-1 documented a final BP reading of 128/78 with a statement that "[t]he patient is being evaluated for resistant or secondary causes for hypertension." PCP-1 documented that the HTN was controlled and made no medication changes. PCP-1 ordered an electrocardiogram (EKG) for "[labile hypertension](#)." No acute changes were reported on the EKG. PCP-1 requested a nine-month follow-up appointment.

The initial high readings were not likely to have represented false readings as the first two readings were in the left arm and the third reading was completed on the right arm. The nine-month follow-up appointment without monitoring was not a safe care plan for Patient W with disease conditions creating risks for coronary events. A closer follow-up with BP surveillance, HTN management, and possible intervention may have prevented Patient W's myocardial infarction. Patient W's coronary event did not change PCP-1's approach to management of this patient's care or affect routinely documenting 128/78 as the final BP.

Patient X did not receive sufficient surveillance of elevated BPs. Patient X had a recent stroke; closer monitoring and management of BPs would have lowered risks for another stroke. Stroke management may also be affected by the type of stroke, [hemorrhagic](#) or [ischemic](#), that occurred.

²⁴ "Out-of-office measurement of BP can be helpful for confirmation and management of hypertension. Self-monitoring of BP refers to the regular measurement of BP by the patient at home or elsewhere outside the clinic setting." Paul K. Whelton, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines.

The OIG noted that PCP-1 incorrectly documented Patient X had an ischemic stroke treated with tPA. The CT reflected a hemorrhagic stroke with midline shift. The use of tPA is contraindicated in a hemorrhagic stroke as it can worsen the bleeding in the brain. This was a basic but significant error in PCP-1's record of care as subsequent clinical providers could rely upon this incorrect information in deciding therapy for future stroke management.

Patient Y was partially blind from a previous stroke. In each of three clinic visits with PCP-1, elevated BPs were recorded and resulted in the same number (128/78) after each recheck. PCP-1 did not add stroke to Patient Y's problem list although multiple follow-up appointments did occur after the vision loss. The OIG could not ascertain from the EHR review whether PCP-1 recognized that a stroke event occurred for Patient Y. Patients with completed strokes benefit from controlled BPs to prevent second strokes.

The OIG team provided detailed information about these cases to Facility leaders at the time of the site visit.

ASCVD Risk Calculator Results

In assessing the risk of harm from PCP-1's BP falsification and poor management of HTN, the OIG considered the American College of Cardiology (ACC) and American Heart Association (AHA) joint guidelines²⁵ on 10-year risk estimates for developing ASCVD events. An ASCVD event is defined as a first nonfatal myocardial infarction or coronary heart disease, death from coronary heart disease, or fatal or nonfatal stroke. The factors recognized to contribute to the 10-year ASCVD estimate pertain to African-American and white men and women 40 to 79 years of age. The variables in the risk assessment are age, total and high-density lipoproteins (HDL) "good" cholesterol, SBP (treated or untreated), diabetes, and current smoking status. Inadequate treatment of diabetes and HTN will elevate the risk. The result gives a quantitative analysis of risk for a patient who does not have ASCVD at the time of the calculation.

For example, a 65-year-old white male, nonsmoker *with* diabetes, on medications to manage HTN, total cholesterol of 150, and an HDL of 55, the 10-year ASCVD risk associated with specific SBP measurements is tabulated below.

²⁵ Paul K. Whelton, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines.

Table 1 – Example of Specific Systolic Blood Pressure Measurements and 10-Year Risk

SBP	10-year ASCVD Risk (percent)
100	14.1
120	19
140	24.2
160	29.7
180	35.3
200	40.9

Source: ACC/AHA ASCVD 10-year risk calculator

The Table 1 example illustrates that SBP control significantly impacts the 10-year risk of an ASCVD event.

Of the 64 high-risk patients reviewed by the OIG physician, all had diagnoses of HTN and diabetes; the BP measurements were $\geq 160/100$. Forty-three of these patients were aged 40 to 79 and met the criteria to apply the ASCVD calculator. According to the ASCVD calculator, their collective average 10-year ASCVD risk was 53 percent using their initial BP readings. The patient with the lowest risk was at 24.6 percent and the highest risk was at 82.2 percent. These patients had marked SBP elevations with significant risk factors.

The goal is to try to optimize treatment to achieve the lowest SBP number possible to lower risk, and the ACC/AHA joint guidelines recommend consideration of intervention starting when ASCVD risk is > 7.5 percent. PCP-1’s care plans required different levels of clinical decision-making to optimize future health for the patients. In these 43 patients with uncontrolled HTN and diabetes, inaction, inadequate surveillance, or acceptance that elevated BP numbers were only transient without any confirmation to the contrary, exposed patients to continued risks that could lead to disability or death. PCP-1’s action of systematically applying normal BP readings to patients with high risks for ASCVD events underscored the failure of this provider to deliver basic office-based HTN management and lack of concern in preventing complications of HTN.

PCP-1’s Explanation of Actions

PCP-1 told the OIG team that documenting the 128/78 BP readings would “turn off” clinical reminders, which “keep coming back...they show up every time you see the patient.” PCP-1 reported thinking that the false BP readings entered into notes in the EHR, went to a “dead spot” in the chart. PCP-1 described these actions as “an error” and repeatedly took responsibility. However, PCP-1 did not express concern that the practice of entering fictitious BP readings placed patients at risk until the OIG presented examples (as outlined in the case summaries of

patients W–Y). Specifically, PCP-1 told the OIG team that the LPN assigned to the team would recheck elevated BPs according to clinic protocol and would notify PCP-1 when a second BP was high. PCP-1 implied that unless the LPN reported a persistently high BP on recheck, PCP-1 would not be concerned. On the occasion when PCP-1 rechecked a BP, it was reportedly done in support of the “relationship with the patient” rather than for clinical need.

The OIG team noted that PCP-1 made several assertions and gave explanations for conduct that were either false or illogical:

- Despite PCP-1’s assertion that the LPN rechecked initially elevated BPs and documented the outcome accurately, the LPN (or another qualified staff person) frequently did not recheck BPs. Therefore, the OIG concluded that if PCP-1 relied solely on the LPN to report and document concerning BPs needing attention, this practice placed patients at risk.
- If PCP-1 reviewed previous notes when seeing a patient as reported, PCP-1 would have seen repeated 128/78 BPs. This should have made it clear that these false BPs went into the EHR, not a “dead spot.”
- “Turning off” a clinical reminder would require PCP-1 to enter a BP reading into the clinical reminder screen and then save the entry. The affirmative action of “saving” the entry should have made it clear that the false BPs went into the EHR, not a “dead spot.”
- PCP-1 denied having awareness or understanding of the primary care performance measures, which included the HTN measures used for performance bonuses and clinical privileging. However, PCP-1 told the OIG team about presenting a VHA-wide training session on HTN management and, as such, the OIG concluded that PCP-1 would likely have a basic awareness of the associated performance measures.
- PCP-1 reportedly told the Medical Executive Committee in early 2018 that 128/78 was used as a method to “group” patients needing follow-up and further described this as a nurse or pharmacist follow-up clinic for HTN. However, PCP-1 had not told the clinic staff about this reported plan. The OIG noted that other methods were available to identify patients with elevated BPs requiring follow-up that did not require falsifying EHR documentation to reflect normal BPs (which was advantageous to PCP-1).
- PCP-1 wrote in a letter to the COS in early 2018: “[t]his investigation has identified a data input error on my part but it also served to identify a critical error in the electronic health record that we use – the finding that some Clinical Reminders are changing the medical record by allowing the placement of erroneous data in the

patient’s vital signs.” The OIG team found PCP-1’s characterization of the BP entries as “a data input error” and blaming the EHR for “allowing the placement of erroneous data” to be perplexing.

As PCP-1 did not provide a reasonable explanation of the actions taken or motivations for falsifying BP readings, the OIG team concluded that the most plausible scenario related to workload management. PCP-1 told OIG staff about finishing patient-related documentation typically by 3:30 p.m. each day; however, the OIG found this unusual for a busy PCP needing to document care delivered to patients that day, respond to dozens (if not hundreds) of “view alerts,”²⁶ and prepare for upcoming patient appointments and examinations. Normal and nearly normal BPs as recorded by PCP-1 would not require further intervention or documentation, which would serve to lighten PCP-1’s workload.

Issue 2: Factors That Permitted BP Falsification to Go Undetected and/or Unreported

Performance Measure Data Validation

The Facility did not have processes in place to validate performance measure data. The Facility used a variety of metrics to monitor PCP-1’s performance. PCP-1’s performance in some of those metrics, including HTN management, was a data point used to renew clinical privileges and grant a monetary performance award.

The VHA Support Service Center (VSSC) collects and reports data on 30 statistical metrics related to patients identified with HTN and assigned to a PCP. This data would typically be used by a PCP to evaluate his/her patients’ general responses to treatment for HTN. Primary care managers would use this data to review and compare the summary level performance with the metrics across providers and divisions. One HTN metric involves the number of hypertensive patients [on the PCP’s panel] with SBP \geq 160 or DBP \geq 100 with a goal not to exceed 20 percent.²⁷ In FYs 2016 and 2017, this metric was considered in both the clinical privileging and performance bonus pay processes for PCPs.

Table 2 reflects Berea CBOC PCP performance, as displayed in the VSSC Primary Care Almanac, for the period July 1 through December 31, 2017, for the percentage of hypertensive

²⁶ VHA Directive 1088, *Communicating Test Result to Providers and Patients*, October 7, 2015. Test results must be communicated by the diagnostic provider to the ordering provider, or designee, within a time-frame that allows for prompt attention and appropriate action to be taken. The Computerized Patient Record System (CPRS) based notification system, known also as “view alerts” is the method used to notify the ordering provider (or other providers designated by the ordering provider) that test results are ready for review and clinical follow-up.

²⁷ The BP value used in the metric is the last BP recorded in the vital signs package in the prior 12 months of the applicable timeframe.

patients with SBP \geq 160 or DBP \geq 100. Taken at face value, the HTN performance metric results showed that PCP-1 was meeting targets for managing this population.

Table 2. Percentage of HTN-BP Systolic \geq 160 or Diastolic \geq 100

2017 Berea CBOC	Jul	Aug	Sep	Oct	Nov	Dec
PCP-1	3.5	2.6	2.8	2.3	3	2.4
PCP-2	2.8	1.8	1.1	1.4	1.4	1.5
PCP-3	4.6	4.7	5.6	5	6.1	5
PCP-4	6.9	7.1	7	6.7	6	6.2

Source: OIG analysis of VSSC Primary Care HTN Patient Metrics

Table 3 shows Berea CBOC PCPs’ percentage of patients with SBP \geq 120 and $<$ 130 and DBP $<$ 90. This is generally considered a normal BP and is the category captured with the 128/78 value. The percentage of PCP-1’s normal BP readings is dramatically higher than the peers’ panels despite the similar patient populations.

Table 3. Percentage of HTN-BP Systolic \geq 120 and $<$ 130 and Diastolic $<$ 90

2017 Berea CBOC	Jul	Aug	Sep	Oct	Nov	Dec
PCP-1	53.1	53.2	53.6	57.9	60	64.2
PCP-2	27.5	27.9	28.7	26.9	27.4	25.6
PCP-3	20.2	19.7	18	19.3	20.8	17.9
PCP-4	23.3	23	22.7	23.2	23.7	23.2

Source: OIG analysis of VSSC Primary Care HTN Patient Metrics

In accordance with VHA guidance, Primary Care Management Module (PCMM) coordinators are supposed to validate the accuracy of the data impacting VSSC performance monitor reports monthly.²⁸ However, Facility staff did not take additional steps to validate the underlying data, which would have uncovered PCP-1’s falsified BP documentation and deviation from accepted practices.

Table 4 is an example of the patient specific data that is readily available by clicking on the hyperlinks in the VSSC HTN measures.

²⁸ VHA Handbook 1101.02, *Primary Care Management Module (PCMM)*, April 21, 2009 was rescinded and replaced by VHA Directive 1406, *Patient Centered Management Module (PCMM) for Primary Care*, June 20, 2017. While VHA Handbook 1101.02 specified a monthly review, VHA Directive 1406 does not specify a timeframe for this comparative analysis. VHA Directive 1406 requires “Completing comparative analysis of VSSC reports or data sets with local PCMM data to identify data variance and ensure data integrity.”

Table 4. Example of Patient-Level Data Available in HTN Metric of VSSC

Sex	Age	BP	BP Date	Last PCP Visit
M	31	130/93	3/30/2010	3/30/2010
M	52	128/90	12/22/2009	12/17/2009
M	80	152/69	7/14/2010	7/13/2010
M	60	154/63	8/5/2010	8/5/2010
M	56	158/110	7/13/2010	7/13/2010
M	61	123/92	8/10/2010	7/27/2010
M	75	152/92	8/31/2010	8/31/2010

Source: VHA Primary Care Almanac, page 8; for accessibility, the format of the original table has been modified

A visual scan of PCP-1’s patient-level data would have revealed the pattern of BPs systematically documented as 128/78.

Table 5. PCP-1’s Patient-Level Data for Percentage of HTN BP Systolic \geq 120 and $<$ 130 and Diastolic $<$ 90²⁹

Systolic BP	Diastolic BP	BP Date
128	78	11/13/2017
124	66	7/14/2017
128	78	11/13/2017
128	78	6/8/2017
128	78	10/25/2017
128	78	11/15/2017
128	78	7/17/2017
128	78	3/23/2017
128	78	10/18/2017

Source: VSSC Primary Care HTN Metric; for accessibility, the format of the original table has been modified

Neither the PCMM Coordinator nor the Health Promotion and Disease Prevention (HPDP) Coordinator validated VSSC data for the clinical performance measures. The HPDP Coordinator told OIG staff that he/she only began providing CBOC leaders with a primary care performance

²⁹ Columns in the table have been removed to minimize the potential for specific patient identification.

measure “scorecard”³⁰ in late 2017. PCP-1 reported trying to discuss primary care performance metrics with the team, but implied that this was not a routine occurrence.

The OIG team learned that PCP-1 received about a \$4,500 performance award in 2016, based in small part on an achievement of the HTN measure. PCP-1 did not receive an award in 2017. The HTN metric was also one element of PCP-1’s ongoing professional practice evaluation (OPPE) for clinical privileging. Had PCP-1 not met this measure, re-privileging was still likely assuming other measures and criteria were met; however, it is possible that the supervisor would have provided education and increased monitoring until PCP-1 met the measure.

Berea CBOC Practices and Culture

The Berea CBOC has four PACT teams, and each team’s assigned LPN was typically responsible for taking and documenting vital signs, including BPs. While the CBOC lacked policies and protocols for rechecking initially elevated BPs,³¹ basic nursing practice would still dictate certain actions. Specifically, elevated BPs would necessitate the BP being rechecked and the physician notified of the repeat elevated BP so that a decision could be made about intervention, if indicated. Further, in accordance with VHA documentation requirements, every BP reading should be documented in the EHR.³² This is important because healthcare providers communicate with each other through the EHR, and each health professional involved with patient care formulates a plan with information in the EHR.

PCP-1’s LPN Did Not Consistently Meet VHA Documentation Standards

It did not appear that the LPN assigned to PCP-1’s team was taking appropriate steps to document elevated BPs. The LPN described to the OIG team the LPN’s practice of documenting the initial BP on an encounter form, providing the encounter form to PCP-1 to review, and/or verbally telling PCP-1 if the BP was elevated. The LPN further told OIG inspectors that when rechecking an initially elevated BP, the LPN would only document the “better” BP reading,

³⁰ The scorecard is a PowerPoint presentation reflecting primary care performance measure results by PCP. It includes all PCPs Facility-wide, and PCPs are identified by a random and rotating number rather than by name.

³¹ The protocol might include such elements as which clinician should recheck, how it should be done (manual BP cuff or BP machine), how to position the patient for recheck, and how long to wait before taking a new BP reading.

³² According to VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015, “Under Title 44 United States Code (U.S.C.) 3102(1), VHA, by statute, must maintain complete, accurate, timely, clinically-pertinent, and readily-accessible patient health records, which contain sufficient recorded information to serve as a basis to plan patient care, support diagnoses, warrant treatment, measure outcomes, support education, research, and facilitate performance improvement processes and legal requirements.”

which the LPN defined as the lower value.³³ PCP-1's LPN reported not always rechecking the BP as some patients had already left the clinic.

The LPN's self-described documentation practices were inconsistent with VHA requirements and were contrary to safe and appropriate patient care. In the OIG's review of the patient encounters, when the initial BP was elevated, the LPN frequently failed to electronically document a repeat BP. Further; the OIG team could not confirm that the LPN provided the BP readings to PCP-1 via a hard-copy encounter form as those forms were routinely shredded per CBOC practice.³⁴ The OIG team was not reasonably able to evaluate whether the LPN verbally notified PCP-1 of elevated BPs.

PCP-1's LPN was largely responsible for taking the initial, and in some instances, repeat BPs. As such, this LPN would see the most recent BP reading in the EHR and was in a position to identify the systematic pattern of 128/78 BP readings across patients and time, regardless of patients' medical histories. However, the LPN denied seeing a pattern of BP rechecks documented as 128/78 and reported first becoming aware of the falsifications in late 2017, after PCP-1's conduct was identified. Given the frequency and duration of the BP falsification (1,364 BP readings of 128/78 over several years), the LPN's assertion appears unlikely. The LPN did report, in hindsight, thinking PCP-1 may have documented a BP that clears the clinical reminder.

PCP-1 and the Team's LPN Overlooked Each Other's Poor Practices

The Berea CBOC is a rural clinic where the primary care teams had often worked together for years. PCP-1 worked with the same LPN for about five years, and their support for one another during separate OIG interviews was evident. This apparent loyalty, however, may have negatively affected the professional standards that team members should expect of each other in the care of patients:

- PCP-1 improperly took shortcuts to, apparently, turn off clinical reminders. OIG concluded that it is more likely than not that the LPN knew or suspected PCP-1 was not documenting BPs accurately. Failure to report or address the apparent discrepancies placed patients at risk.
- The LPN improperly took shortcuts if only documenting the "better" BP. Because PCP-1 knew these patients and their medical histories, and reviewed their EHRs prior to appointments, the OIG concluded that it is more likely than

³³ The OIG acknowledges that, on occasion, technical errors can occur. In those limited situations, the potentially erroneous BP would not be documented. The LPN, however, did not qualify a statement of only documenting the "better" of the two BPs when a technical error occurred.

³⁴ This is an approved VA form 10-0360. Its use and destruction are allowed as described in VHA Handbook 1907.01 *Health Information Management and Health Records*. March 19, 2015.

not that PCP-1 knew (or should have known) that the LPN was not rechecking and documenting multiple BPs in accordance with clinic practice and PCP-1's expectations as reported to the OIG. Failure to report or address the apparent discrepancies placed patients at risk.

While the OIG cannot say with certainty that other PACT team members had knowledge of the misdeeds, the repeat BPs of 128/78 were prevalent throughout the EHRs and difficult to miss. The CBOC nurse manager thought that coworkers would speak up to express complaints. However, these serious patient safety concerns were not reported by other PACT team members with shared responsibility for PCP-1's patient caseload.

Issue 3: Leadership Responsiveness to Concerns

The OIG team determined that Facility leaders took prompt and appropriate actions to evaluate PCP-1's actions and mitigate risk to patients. Facility leaders learned of PCP-1's improper BP documentation in late 2017. A PACT Coordinator completed an initial review comparing HTN cohorts using VSSC data that substantiated a highly unlikely trend of 128/78 BP readings in PCP-1's hypertensive patients. Facility leaders subsequently contacted 10 patients who had recently been seen by PCP-1 and learned that PCP-1 had not repeated the BP for at least eight of the patients during their visits.

PCP-1's privileges were summarily suspended and PCP-1 was reassigned to an administrative role in less than seven days pending the outcome of further investigation. PCP-1's patients were reassigned to other providers; the Facility Risk Manager, along with other clinicians, started EHR reviews to assess whether patients were at risk for, or had experienced, adverse clinical outcomes due to the alleged misconduct.

The Facility timely completed an Issue Brief and the COS notified the OIG of the fraudulent documentation concerns as required.

Facility leaders took additional actions:

- Established a HTN clinic in early 2018 to follow-up with PCP-1's patients. By mid-March 2018, all patients in the 128/78 cohort had been contacted by letter and/or phone to arrange follow-up.
- Conducted reviews of patients on PCP-1's panel who had ED visits between June 1 and December 26, 2017, to evaluate for adverse clinical outcomes.
- Referred appropriate cases for external review looking specifically at PCP-1's management of HTN in the primary care setting.
- Initiated an expedited, five-day, State Licensure Board report.
- Conducted a clinical disclosure to one patient who suffered a heart attack.

- Discussed PCP-1's privileges at the Medical Executive Committee, during which PCP-1 provided input into the proceedings.
- Discussed concerns with General Counsel and met several times with PCP 1.

Per Human Resource Management staff, the Facility is in the process of evaluating administrative actions related to PCP-1, as appropriate.

Conclusion

PCP-1 frequently documented repeat BP readings of 128/78 after initially elevated BP readings. These falsifications occurred across hundreds of patients and over multiple years. The patients included in OIG's EHR review population were at high risk for adverse clinical outcomes due to uncontrolled HTN and multiple co-morbid conditions. One patient experienced a heart attack and two others were placed at risk for second strokes due to PCP-1's poor HTN management practices, including minimal medication changes even in instances when it would have been appropriate. Also, the OIG team's EHR review found that PCP-1 inconsistently completed laboratory orders when medications were added; recommended nine-month follow-up appointments irrespective of the patients' conditions; documented secondary HTN with no evidence of a workup; and rarely documented that home BP cuffs were issued, even though PCP-1 reported this was a regular HTN management approach.

OIG further confirmed PCP-1's poor HTN management practices by applying the ACC/AHA 10-year risk calculator to develop ASCVD. In a subset of high-risk patients reviewed, the OIG determined that the collective average 10-year ASCVD risk was 53 percent using their patients' initial BP readings, with a low of 24.6 percent and a high of 82.2 percent. The goal is to try to optimize treatment, and ACC/AHA joint guidelines recommend consideration of intervention starting when ASCVD risk is > 7.5 percent. PCP-1's inaction and inadequate surveillance related to HTN exposed patients to continued risk.

PCP-1 told the OIG team of documenting the 128/78 BP readings to "turn off" the clinical reminder and provided several rationales for this conduct. The OIG team did not find the explanations plausible.

The Facility did not have processes in place to validate performance measure data. Per VHA guidance, PCMM coordinators are supposed to validate the accuracy and integrity of data impacting VSSC performance monitors. However, the Facility staff did not take additional steps to validate the underlying data, which would have uncovered PCP-1's troubling pattern of falsified BP documentation and deviation from accepted practices.

The OIG team had additional concerns, including that the Berea CBOC lacked policies and protocols for rechecking initially elevated BPs, and PCP-1's LPN told OIG of only documenting the "better" (lower) reading when rechecking BPs, which is inconsistent with VHA policy. PCP-1's LPN was largely responsible for taking the initial, and in some instances, repeat BPs. As such, this LPN would see the most recent BP reading in the EHR and was in a position to identify the systematic pattern of 128/78 BP readings across patients and time, regardless of patients' medical histories. However, the LPN denied seeing a pattern of BP rechecks documented as 128/78 and reported first becoming aware of the falsifications in late 2017, after PCP-1's conduct was identified.

Once they became aware of the issue, Facility leaders took prompt and appropriate actions to evaluate PCP-1's actions and mitigate risk to patients. PCP-1's clinical privileges were suspended, and patients were reassigned to other primary care providers. Facility leaders established an HTN clinic to follow-up with PCP-1's patients; initiated appropriate clinical reviews; initiated a State Licensure Board report; and conducted a clinical disclosure. The Facility is evaluating the initiation of administrative actions related to PCP-1, as appropriate.

The OIG made seven recommendations.

Recommendations 1–7

1. The Lexington VA Medical Center Director takes administrative action in relation to primary care provider 1, as appropriate.
2. The Lexington VA Medical Center Director ensures patients impacted by blood pressure falsifications are evaluated and followed up.
3. The Lexington VA Medical Center Director evaluates and takes appropriate action in relation to the four cases discussed in this report.
4. The Lexington VA Medical Center Director develops processes to ensure the integrity of Veterans Health Administration Support Service Center data that supports performance metrics.
5. The Lexington VA Medical Center Director ensures the development of policies and procedures governing primary care-based blood pressure readings and documentation.
6. The Lexington VA Medical Center Director evaluates the practices of primary care provider 1's licensed practical nurse, and takes appropriate administrative action, if indicated.
7. The Lexington VA Medical Center Director requires retraining of Berea Community Based Outpatient Clinic staff on documentation requirements.

Appendix A: Patient Case Summary

Patient Z

Patient Z, a patient over 50, had a history of right upper extremity [osteosarcoma](#), a form of bone cancer. Patient Z enrolled into PCP-1's clinic in July 2010. In 2010, PCP-1 evaluated Patient Z for right elbow pain and imaging tests confirmed a mass. After referral to a non-VA orthopedic oncologist, Patient Z underwent surgery for an osteosarcoma in early 2011.

In mid-2014, PCP-1 saw Patient Z and noted drainage from the right arm since an original surgery. PCP-1 documented Patient Z's magnetic resonance imaging (MRI) earlier in 2014 was normal. The last MRI completed prior to this visit was in late 2013 and showed no evidence of recurrent disease. On physical exam, PCP-1 described drainage from an entry point to the right elbow that appeared to channel into deeper structures. PCP-1 prescribed antibiotics, documented the possible need for surgical evaluation, and scheduled Patient Z for a nine-month follow-up appointment.

In mid-2015, PCP-1 saw Patient Z, documenting a 1cm open ulcer on the elbow; PCP-1 requested a nine-month follow-up appointment.

During the spring 2016, PCP-1 saw the patient and documented, "[Patient] has not been seen by [the] Orthopedic Oncologist in three or four years and [he/she] is thought [sic] to be in full remission from [his/her] [mast cell sarcoma](#) of the right upper extremity." PCP-1 documented, "Sarcoma right upper extremity limited f/u [follow up] with oncologist, felt to be in remission." PCP-1 requested a nine-month follow-up appointment.

In late 2016, Patient Z called a CBOC nurse to complain of a lump to the right elbow. PCP-1 requested that Patient Z go to the ED for a CT scan, the reported findings of which were consistent with cancer recurrence to the right arm. PCP-1 entered an orthopedic consult. In early 2017, the orthopedic surgeon ordered an MRI which was completed the following month. The results revealed a large destructive lesion indicating the possibility of a recurrence of malignancy in the same area of the original tumor.

In early 2017, the orthopedic surgeon evaluated Patient Z and, when referring to the MRI results, documented that there was no evidence of tumor recurrence. The orthopedic surgeon's plan reflected that there was no evidence of tumor recurrence and that Patient Z was to follow up as needed.

During the summer 2017, Patient Z called with complaints of persistent right elbow drainage. The orthopedist evaluated the patient and ordered a follow-up MRI. The MRI completed a week later reported,

Impression: Worsening appearance of the elbow joint which is nonspecific and could represent recurrent tumor or [osteomyelitis](#) with abscess extending into the

soft tissues along the medial aspect of the elbow cannot be excluded as described in detail above.

In late 2017, the orthopedic surgeon evaluated Patient Z for follow-up and performed a [tissue biopsy](#). The results noted recurrence of the tumor and further workup noted no evidence of [metastatic disease](#). Patient Z underwent a right upper extremity amputation for the recurrent osteosarcoma.

OIG Analysis

The OIG had concerns related to the clinical management of Patient Z's osteosarcoma by PCP-1 and the Facility's orthopedic surgeon. In the 2014 and 2015 appointments, PCP-1 documented unresolved healing related to the right elbow; however, the plans of care did not include closer surveillance. Unresolved healing to the surgical site in the same area where cancer occurred required closer monitoring and more recent imaging. The OIG also noted that the orthopedic surgeon in the early 2017 appointment documented inaccurate information about the MRI results and subsequently relayed inaccurate information to Patient Z. The inaccurate details of the MRI report given to the patient may have resulted in a delay in diagnosis and treatment of recurrent osteosarcoma.

Appendix B: Glossary of Terms

An **aortic aneurysm** is an abnormal bulge that occurs in the wall of the major blood vessel that carries blood from the heart to the body.

An **artery** is a vessel through which the blood passes away from the heart to various parts of the body.

Cardiac bypass surgery is a surgical procedure that diverts the flow of blood around a section of a blocked or partially blocked artery in the heart.

Cardiac stents are small wire mesh tubes to help prop an artery open and decrease its chance of narrowing.

Cholesterol is a waxy substance that is found in the fats in blood.

Computed Tomography scan (CT) combines a series of x-ray images taken from different angles and uses computer processing to create cross-sectional images or slices, of the bones, blood vessels, and soft tissues inside the body.

Congestive heart failure occurs when the heart muscle does not pump blood as well as it should.

Diabetes refers to a group of diseases that affect how the body uses blood sugar.

An **electrocardiogram (ECG or EKG)** records the electrical signals in the heart. It is a common test to detect heart problems and monitor the heart's status in many situations.

Heart catheterization is a procedure used to diagnose and treat cardiovascular conditions.

Labile hypertension occurs when there is a substantial increase in BP. The increases often, but not always, occur in the setting of emotional distress, particularly anxiety. Labile hypertension can be asymptomatic or can be accompanied by symptoms such as headache, palpitations, or flushing.

Licensed Practical Nurses work under the supervision of registered nurses and are responsible for providing basic nursing care.

Magnetic Resonance Imaging (MRI) is a technique that uses a magnetic field and radio waves to create detailed images of the organs and tissues within the body.

Metastasis is the spread of cancer cells from the place where they first formed to another part of the body.

Mid line shift is the lack of blood flow resulting in severe damage to some of the brain tissue. The damaged tissue causes fluids to accumulate and results in swelling. The center of the brain is shifted due to an increase in swelling.

Myocardial infarction (heart attack) occurs when cell death results in damaged or destroyed heart tissue.

Neurologist is a physician skilled in the diagnosis and treatment of diseases of the nervous system.

Osteomyelitis is an infection in the bone.

Osteosarcoma is the most common type of bone cancer. It is most often found in the long bones but sometimes the arms.

Registered Nurse is a graduate trained nurse who has been licensed by a state authority after passing qualifying examinations for registration. The registered nurse has more training and experience than a licensed practical nurse.

Sarcoma is a type of cancer that starts in bone or muscle. Sarcomas that start in the bones are called osteosarcomas.

Stroke is when the blood supply to part of the brain is interrupted or reduced, depriving brain tissue of oxygen and nutrients.

- a) Ischemic stroke occurs when arteries to the brain become narrowed or blocked, causing severely reduced blood flow.
- b) Hemorrhagic stroke occurs when a blood vessel in the brain leaks or ruptures.
- c) Intracerebral hemorrhage occurs when a blood vessel in the brain bursts and spills into the surrounding brain tissue, damaging brain cells.

Thrombus is a blood clot.

Tissue biopsy is a sample of tissue that is used to identify and diagnose abnormalities in cells.

Tissue plasminogen activator (tPA) is a blood clot-dissolving drug.

Appendix C: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: August 30, 2018

From: Director, VA MidSouth Healthcare Network (10N9)

Subj: Healthcare Inspection—Falsification of Blood Pressure Readings at the Berea Community Based Outpatient, Lexington, Kentucky

To: Director, Rapid Response, Office of Healthcare Inspections (54RR)

Director, Management Review Service (VHA 10E1D MRS Action)

1. I have reviewed the findings and recommendations in the OIG report entitled, Draft Report: Falsification of Blood Pressure Readings at the Berea CBOC, Kentucky. I concur with the action plans submitted by the Lexington Medical Center Director, with the request for closure of 5 of 7 recommendations.
2. An employee contacted the supervisor with the concerns. The issue was elevated to Medical Center and VISN leadership. A review was conducted immediately resulting in the removal of the provider from clinical care.
3. We value psychological safety among our employees and appreciate them recognizing and reporting the issue. The Medical Center leadership took prompt action upon notification of the problem and in the interest of transparency, contacted the OIG. We thank the OIG for their review and response to what we discovered.
4. If you have any questions or require additional information, please contact Angela Malik, Quality Management Officer at 615-695-2143.

(Original signed by:)

Cynthia Breyfogle, FACHE

Network Director

Appendix D: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: August 30, 2018

From: Director, Lexington VA Medical Center (596/00)

Subj: Healthcare Inspection—Falsification of Blood Pressure Readings at the Berea Community Based Outpatient Clinic, Lexington, Kentucky

To: Director, VA MidSouth Healthcare Network (10N9)

An employee at the Berea, KY VA Outpatient Clinic notified their supervisor with concerns that a provider may be falsely recording blood pressure measurements in the veterans' medical records. The supervisor immediately notified facility leadership. Leadership promptly notified the VISN. Actions were implemented to remove the provider from clinical care and a thorough investigation of the allegations was executed. Subsequently, the OIG was notified of the expressed concerns.

Thank you for the opportunity to review and respond to the OIG recommendations in the draft report, Healthcare Inspection—Falsification of Blood Pressure Readings at the Berea CBOC, Kentucky. I concur with the findings and recommendations.

Our responses to the report recommendations are attached. We have been actively working on improvements. We appreciate the perspective from the Office of Inspector General and will take this opportunity to strengthen and improve our medical processes.

(Original signed by:)

Emma Metcalf, MSN, RN

Comments to OIG's Report

Recommendation 1

The Lexington VA Medical Center Director takes administrative action in relation to primary care provider 1, as appropriate.

Concur.

Target date for completion: 07/06/2018

Director Comments

Administrative action was taken by the target date, resulting in termination of PCP-1. We request closure of this recommendation.

OIG Comment: The Facility provided sufficient supporting documentation, and the OIG considers this recommendation closed.

Recommendation 2

The Lexington VA Medical Center Director ensures patients impacted by blood pressure falsifications are evaluated and followed up.

Concur.

Target date for completion: 01/09/2018

Director Comments

All patients impacted by the blood pressure falsifications were contacted by letter and/or phone to arrange follow-up in a hypertension clinic established in early 2018. All patients were assigned to a new primary care provider for further management in early 2018. Patients are being followed in their assigned clinics. We request closure of this recommendation.

OIG Comment: The Facility provided sufficient supporting documentation, and the OIG considers this recommendation closed.

Recommendation 3

The Lexington VA Medical Center Director evaluates and takes appropriate action in relation to the four cases discussed in this report.

Concur.

Target date for completion: 08/03/2018

Director Comments

On July 25, 2018, an Institutional Disclosure was completed for patient Y in the report and a Clinical Disclosure was completed for Patient Z. On August 3, 2018 Institutional Disclosures were completed for patients W and X. We request closure of this recommendation.

OIG Comment: The Facility provided sufficient supporting documentation, and the OIG considers this recommendation closed.

Recommendation 4

The Lexington VA Medical Center Director develops processes to ensure the integrity of Veterans Health Administration Support Service Center data that supports performance metrics.

Concur.

Target date for completion: 9/1/2019 to allow time for monitoring.

Director Comments

On December 27, 2017, Chief of Staff completed a review of all primary care providers blood pressure results for their panels, ensuring there were no other patterns similar to PCP-1's PACT. To further ensure the integrity of VSSC data, the PCMM Coordinator or designee will begin validating VSSC data, and PC provider OPPE cycle data. Validation of data will occur every six months, beginning with the next OPPE cycle on October 1, 2018. Data will be reported on a biannual basis in Primary Care Provider Meeting and Health Care Delivery Council to ensure ongoing compliance.

Recommendation 5

The Lexington VA Medical Center Director ensures the development of policies and procedures governing primary care-based blood pressure readings and documentation.

Concur.

Target date for completion: 08/03/2018

Director Comments

There were policies and procedures in place governing management of patients with hypertension which included monitoring blood pressure and documentation standards for nursing. February through March 2018 during nursing skills fair, all RN's and LPN's were educated on diabetes and hypertension population management, using a step by step standard work tool and competency validation tool. To further strengthen the expected practice, on August 2, 2018, Berea CBOC nursing members were re-educated on proper procedure to perform and record blood pressure measurements per the standard work skill validation tool.

August 3, 2018, Primary Care leadership re-educated Berea CBOC providers, on the existing policy for management of the patient with hypertension and on documentation. Because policies and procedures were in place and now have been reinforced, we request closure of this recommendation.

OIG Comment: The OIG will keep this recommendation open to allow time for the Facility to monitor compliance.

Recommendation 6

The Lexington VA Medical Center Director evaluates the practices of primary care provider 1's licensed practical nurse, and takes appropriate administrative action, if indicated.

Concur.

Target date for completion: 12/01/2018

Director Comments

Nursing Leadership has reviewed PCP-1's LPN practice since the initial education and validation of competency for blood pressure measurement and recording was validated and signed on 3/23/18. Random chart audit of PCP-1's LPN for blood pressure measurement and documentation practice compliance from 3/23/18 to 7/25/18 was completed on 7/27/18. Based on the OIG review evidence, and the recent random chart audit evidence, Human Resources was consulted on 7/27/18 to determine the appropriate disciplinary action for PCP1's LPN.

Recommendation 7

The Lexington VA Medical Center Director requires retraining of Berea Community Based Outpatient Clinic staff on documentation requirements.

Concur.

Target date for completion: 08/03/2018

Director Comments

On August 1, 2018, Berea CBOC nursing staff was retrained on documentation requirements. On August 3, 2018, Berea CBOC providers staff was retrained on documentation requirements. We request closure of this recommendation.

OIG Comment: The Facility provided sufficient supporting documentation, and the OIG considers this recommendation closed.

OIG Contact and Staff Acknowledgments

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